REMARKS

Reconsideration and withdrawal of the restriction requirement is respectfully requested in view of the remarks made herewith, which place the application into condition for allowance.

The Examiner has required restriction from among the following groups:

I. Claims 1-3, 10-15, 16, 20, and 21, drawn to a polypeptide or peptide comprising the amino acid sequence in SEQ ID NO. 16 or SEQ ID NO. 26, and the ligand or compound that increases or decreases the level of expression or activity of SEQ ID NO. 16 or SEQ ID NO. 26, classified in class 530, subclass 350+.

II. Claims 4-9, and 17-19, drawn to a purified nucleic acid molecule as recited in SEQ ID NO. 15, SEQ ID NO. 19, SEQ ID NO. 21, SEQ ID NO. 25 or is a redundant equivalent or fragment thereof, the vector comprising the sequences, and the host cell transformed with the vector, classified in class 435, subclass 320.1.

III. Claims 22-30, drawn to a method of diagnosing a disease in a patient comprising comparing the level of expression a natural gene which encodes a polypeptide of SEQ ID NO. 16 or SEQ ID NO. 26 to a control level, wherein a level that is different to the control level is indicative of disease, classified in class 536, subclass 23.1.

IV. Claims 22-30, drawn to a method of diagnosing a disease in a patient comprising comparing the level of expression or activity of a polypeptide of SEQ ID NO. 16 or SEQ ID NO. 26 to a control level, wherein a level that is different to the control level is indicative of disease, classified in class 536, subclass 23.1.

V. Claim 31, drawn to a method of using a polypeptide of SEQ ID NO. 16 or SEQ ID NO. 26 as an antagonist of cytokine expression and/or secretion, classified in class 530, subclass 350+.

VI. Claims 32 and 38, drawn to a pharmaceutical composition and a vaccine composition comprising a polypeptide of SEQ ID NO. 16 or SEQ ID NO. 26, classified in class 530, subclass 350+.

VII. Claims 33-35 and 39, drawn to a pharmaceutical composition and a vaccine composition comprising a nucleic acid molecule of SEQ ID NO. 15, SEQ ID NO.

19, SEQ ID NO. 21, SEQ ID NO. 25, a vector, and a host cell, classified in class 435, subclass 320.1.

VIII. Claim 40, 44, and 45, drawn to a method of using a polypeptide of SEQ ID NO. 16 or SEQ ID NO. 26, a ligand, or a compound, in the manufacture of a medicament for the treatment of an autoimmune disease, viral or acute liver disease, including alcoholic liver failure, or inflammatory disease, classified in class 530, subclass 350+.

IX. Claims 41-43, drawn to a method of using a nucleic acid of SEQ ID NO. 15, SEQ ID NO. 19, SEQ ID NO. 21, SEQ ID NO. 25, the vector, and the host cell, in the manufacture of a medicament for the treatment of an autoimmune disease, viral or acute liver disease, including alcoholic liver failure, or inflammatory disease, classified in class 536, subclass 23.1

X. Claim 46, drawn to a method of using a pharmaceutical composition in the manufacture of a medicament for the treatment of an autoimmune disease, viral or acute liver disease, including alcoholic liver failure, or inflammatory disease, classified in class 514, subclass 44.

XI. Claim 47-49, 59-64, drawn to a method of treating a disease in a patient, comprising administering to the patient a polypeptide of SEQ ID NO. 16 or SEQ ID NO. 26, classified in class 530, subclass 350.

XII. Claims 50-58, drawn to a method of treating a disease in a patient, comprising administering to the patient a nucleic acid of SEQ ID NO. 15, SEQ ID NO. 19, SEQ ID NO. 21, SEQ ID NO. 25, a vector, or a host cell transformed with a vector, classified in class 536, subclass 23.1 or in class 424, subclass 93.1+.

XIII. Claims 65-67, drawn to a method of treating a disease in a patient, comprising administering to the patient a pharmaceutical composition, classified in class 530, subclass 350 or class 424, subclass 93.1+.

XIV. Claim 68, drawn to a method of monitoring the therapeutic treatment of disease in a patient, comprising monitoring the expression level of activity of a polypeptide of SEQ ID NO. 16 or SEQ ID NO. 26, classified in class 530, subclass 350.

XV. Claim 69, drawn to a method of monitoring the therapeutic treatment of disease in a patient, comprising monitoring the expression level of a nucleic acid of SEQ ID

NO. 15, SEQ ID NO. 19, SEQ ID NO. 21, SEQ ID NO. 25, classified in class 536, subclass 23.1.

XVI. Claim 70, drawn to a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease, comprising contacting a polypeptide of SEQ ID NO. 16 or SEQ ID NO. 26, classified in class 530, subclass 350+.

XVII. Claim 71, drawn to a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease, comprising contacting a nucleic acid sequence of SEQ ID NO. 15, SEQ ID NO. 19, SEQ ID NO. 21, SEQ ID NO. 25, classified in class 536, subclass 23.1.

XVIII. Claims 72-74, drawn to a kit used to diagnose a disease comprised of nucleic acids that hybridize with nucleic acids of SEQ ID NO. 15, SEQ ID NO. 19, SEQ ID NO. 21, SEQ ID NO. 25, classified in class 536, subclass 23.1.

XIX. Claim 75, drawn to a kit of one or more antibodies that bind to a polypeptide of SEQ ID NO. 16 or SEQ ID NO. 26, and a reagent used to detect the binding reaction between antibody and polypeptide, classified in class 424, subclass 130.1+.

XX. Claim 76 and 77, drawn to a transgenic or knockout non-human animal, with higher, lower, or absent levels of polypeptide of SEQ ID NO. 16 or SEQ ID NO. 26 and the method of using the animal to screen for compounds to treat disease, classified in class 800, subclass 3 and 8.

Applicants hereby elect the invention of Group I, with traverse, for prosecution on the merits.

Groups I and II are allegedly unrelated because Group I does not depend upon Group II to function and vice versa. Group I relates to a polypeptide or peptide comprising the amino acid sequence presented as SEQ ID NOS 16 or 26, and the ligand or compound that increases or decreases the level of expression or activity of SEQ ID NOS 16 or 26. Group II is to a purified nucleic acid molecule as recited in SEQ ID NOS 15, 19, 21, or 25, or is a redundant equivalent or fragment thereof, the vector comprising the sequences, and the host cell transformed with the vector.

Groups III and IV are allegedly unrelated because Group III does not depend on Group IV to function, and vice versa. The Office Action contends that while the different groups are to a method of diagnosing a disease in a patient, Group III relates to comparing the level of gene expression and Group IV relates to comparing the level of protein expression or activity of a protein.

Groups VI and VII are allegedly unrelated because Group VI does not depend on Group VII to function and vice versa. While the different groups are to pharmaceutical compositions and vaccine compositions, the Office Action states that Group VI is comprised of a polypeptide and Group VII is comprised of a nucleic acid molecule.

Groups VIII, IX, and X are allegedly unrelated because Group VIII is to a polypeptide, Group IX is to a nucleic acid, and Group X is to a pharmaceutical composition. While the different groups are to a method of using a compound in the manufacture of a medicament in the treatment of an autoimmune disease, viral or acute liver disease, including alcohol liver failure, or inflammatory disease, the compounds are unique and distinct and require different methods and reagents.

Groups XI, XII, and XIII are allegedly unrelated because while the different groups are drawn to a method of treating a disease in a patient, Group XI comprises administering a polypeptide, Group XII comprises administering a nucleic acid, and Group XIII comprises administering a pharmaceutical composition.

Groups XIV and XV are allegedly unrelated because while the different groups are to a method of monitoring the therapeutic treatment of disease in a patient, Group XIV comprises monitoring the expression level or activity of a polypeptide and Group XV comprises monitoring the expression level of a nucleic acid.

Groups XVI and XVII are allegedly unrelated because while the different groups are to a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease, Group XVI comprises contacting a polypeptide and Group XVII comprises contacting a nucleic acid.

Groups XVIII and XIX are allegedly unrelated because while the different groups are to kits, Group XVIII relates to a kit that diagnoses a disease using nucleic acids, while Group XIX relates to a kit comprised of antibodies.

Groups VI/VII, VIII/IX/X, and XI/XII/XIII are allegedly related as process of making and process of using the product. The Office Action alleges that the use as claimed cannot be practiced with a materially different product. However, since the product was not allowable, the Office Action required restriction between the process of making and process of using the product.

Groups I/II and II/IV are allegedly related as product and process of use. The Office Action states that in addition to its use to diagnose a disease in a patient, Groups I/II can be used in a pharmaceutical composition. Groups I/II and V are allegedly related as product and process of use. Group II relates to nucleic acids that are materially different and unrelated to Groups I and V. Further, the Office Action states that Group I can be used in a pharmaceutical composition and a vaccine composition.

Groups I/II and V are alleged related as product and process of use. The Office Action states that Group II is to nucleic acids that are materially different and unrelated to Groups I and V. Group I can be used in a pharmaceutically composition and a vaccine composition.

Groups I/II and VI/VII are allegedly related as product and process of use. The Office Action contends that Groups I/II can be used in a method of diagnosing a disease in a patient.

Groups I/II and VIII/IX/X are allegedly related as product and process of use. The Office Action states that Groups I/II can be used in a method of diagnosing a disease in a patient.

Groups I/II and XI/XII/XIII are allegedly related as product and process of use. According to the Office Action, Group I/II can be used in a method of diagnosing a disease in a patient.

Groups I/II and XIV/XV are allegedly related as product and process of use. The Office Action states that Group I/II can be used in a method of diagnosing a disease in a patient.

Groups I/II and XVI/XVII are allegedly related as product and process of use. Group I/II can be used in a pharmaceutical composition, according to the Office Action.

Groups I/II and XX are allegedly unrelated, as Groups I/II are to polypeptides and nucleic acids. Group XX is drawn to a transgenic animal with higher, lower, or absent levels of polypeptide. The Office Action contends that the methods used to study Groups I/II are materially different from those used to study Group XX.

Groups III/IV and V are allegedly unrelated. Groups III/IV are to methods of diagnosing a disease in a patient, while Group V is to a method of using a polypeptide as an antagonist of cytokine expression and/or secretion.

Groups III/IV and VI/VII are allegedly unrelated because Groups III/IV do not depend on Groups VI/VIII to function and vice versa. Groups III/IV are to methods of diagnosing a disease in a patient. Group VI/VII is to a pharmaceutical composition and a vaccine composition.

Groups III/IV and VIII/IX/X are allegedly unrelated because Groups III/IV are to methods of diagnosing a disease in a patient. Groups VIIII/IX/X are to methods of using a pharmaceutical composition in the manufacture of a medicament. The Office Action contends that Groups III/IV do not depend on Groups VIII/IX/X to function and vice versa.

Groups III/IV and XI/XII/XIII are allegedly unrelated because Groups III/IX do not depend on Groups XI/XII/XIII to function and vice versa. Groups III/IV are drawn to methods of diagnosing a disease in a patient. Groups XI/XII/XIII are to a method of treating a disease in a patient.

Groups III/IV and XIV/XV are allegedly unrelated, because Groups III/IV do not depend on Groups XIV/XV to function and vice versa. Groups III/IV are to methods of diagnosing a disease in a patient, while Groups XIV/XV are to methods of monitoring the therapeutic treatment of disease in a patient.

Groups III/IV and XVI/XVII are allegedly unrelated because Groups III/IV are to methods of diagnosing a disease in a patient, and Groups XVI/XVII are to methods of identifying a compound that is effective in the treatment and/or diagnosis of a disease.

Groups III/IV and XVIII/XIX are allegedly related as product and process of use. The Office Action contends that Groups XVIII/XIX can be used in a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease.

Groups III/IV and XX are allegedly unrelated because Groups III/IV are to methods of diagnosing a disease in a patient. Group XX is to a transgenic knockout non-human animal.

Groups V and VI/VII are allegedly unrelated because Group V does not depend on Groups VI/VII to function and vice versa. Group V is to a method of using a polypeptide as an antagonist of cytokine expression and/or secretion. Group VI/VII is drawn to a pharmaceutical composition and a vaccine composition.

Groups V and VIII/IX/X are allegedly unrelated because Group V is to a method of using a polypeptide as an antagonist of cytokine expression and/or secretion, while Groups VIII/IX/X are to a method of using a pharmaceutical composition in the manufacture of a medicament.

Groups V and XI/XII/XIII are allegedly unrelated because Group V does not depend upon Group XI/XII/XIII to function and vice versa. Group V is to a method of using a polypeptide as an antagonist of cytokine expression and/or secretion, while Groups XI/XII/XIII are to a method of treating a disease in a patient.

Groups V and XIV/XV are allegedly unrelated because Group V is drawn to a method of using a polypeptide as an antagonist of cytokine expression and/or secretion and Groups XIV/XV are to a method of monitoring the therapeutic treatment of disease. Group V allegedly does not depend on Groups XIV/XV to function and vice versa.

Groups V and XVI/XVII are allegedly unrelated because Group V is to a method of using a polypeptide as an antagonist of cytokine expression and/or secretion, and Groups XVI/XVII are to a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease.

Groups V and XVII/XIX are allegedly unrelated because Group V does not depend on Groups XVIII/XIX to function and vice versa. Group V is to a method of using a polypeptide as an antagonist of cytokine expression and/or secretion. Groups XVII/XIX are drawn to a kit used to diagnose a disease and a kit to identify polypeptides.

Groups V and XX are allegedly unrelated because Group V relates to a method of using a polypeptide as an antagonist of cytokine expression and/or secretion. Group XX is drawn to a transgenic or knockout non-human animal.

Groups VI/VII and XIV/XV are allegedly unrelated because Groups VI/VII do not depend on Groups XIV/XV to function and vice versa. Groups VI/VII are drawn to a pharmaceutical composition and a vaccine composition, while Groups XIV/XV are drawn to a method of monitoring the therapeutic treatment of disease in a patient.

Groups VI/VII and XVI/XVII are allegedly unrelated because Groups VI/VII do not depend on Groups XVI/XVII to function and vice versa. Groups VI/VII are to a pharmaceutical composition and a vaccine composition, while Groups XVI/XVII are to a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease.

Groups VI/VII and XVII/XIX are allegedly unrelated because Groups VI/VII do not depend on Groups XVIII/XIX to function and vice versa. Groups VI/VII are to a pharmaceutical composition and a vaccine composition. Groups XVII/XIX are drawn to a kit used to diagnose a disease and a kit to identify polypeptides.

Groups VI/VII and XX are allegedly unrelated because Groups VI/VII are to a pharmaceutical composition and a vaccine composition and Group XX is to a transgenic or knockout non-human animal. Groups VI/VII do not depend on Group XX to function and vice versa.

Groups VIII/IX/X and XIV/XV are allegedly unrelated because Groups VIII/IX/X are drawn to a method of using a pharmaceutical composition in the manufacture of a medicament. Groups XIV/XV are drawn to a method of monitoring the therapeutic treatment of disease in a patient.

Groups VIII/IX/X and XVI/XVII are allegedly unrelated because Groups VIII/IX/X do not depend on Groups XVI/XVII to function and vice versa. Groups VIII/IX/X relate to methods of using a pharmaceutical composition in the manufacture of a medicament. Groups XVIII/XIX are to a kit used to diagnose a disease and a kit to identify polypeptides.

Groups VIII/IX/X and XVII/XIX are allegedly unrelated because Groups VIII/IX/X do not depend on Groups XVIII/XIX to function and vice versa. Groups VIII/IX/X relate to a method of using a pharmaceutical composition in the manufacture of a medicament. Groups XVIII/XIX are drawn to a kit used to diagnose a disease and a kit to identify polypeptides.

Groups VIII/IX/X and XX are allegedly unrelated because Groups VIII/IX/X do not depend on Group XX to function and vice versa. Groups VIII/IX/X are drawn to a method of using a pharmaceutical composition in the manufacture of a medicament. Group XX relates to a transgenic or knockout non-human animal.

Groups XI/XII/XIII and XIV/XV are allegedly unrelated because Groups XI/XII/XIII are drawn to a method of treating a disease in a patient, while Groups XIV/XV are drawn to a method of monitoring the therapeutic treatment of disease in a patient.

Groups XI/XII/XIII and XVI/XVII are allegedly unrelated because Groups XI/XII/XIII do not depend on Group XVI/XVII to function and vice versa. Groups XI/XII/XIII relate to a method of treating a disease in a patient. Groups XVI/XVII are drawn to a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease.

Groups XI/XII/XIII and XVIII/XIX are allegedly unrelated. The Office Action contends that Groups XI/XII/XIII do not depend on Groups XVIII/XIX to function and vice versa. Groups XI/XII/XIII relates to a method of treating a disease in a patient. Groups XVIII/XIX are drawn to a kit used to diagnose a disease and a kit to identify polypeptides.

Groups XI/XII/XIII and XX are allegedly unrelated because Groups XI/XII/XIII do not depend on Group XX to function and vice versa. Groups XI/XIII/XIII are drawn to a method of treating a disease in a patient, while Group XX relates to a transgenic or knockout non-human animal.

Groups XIV/XV and XVI/XVII are allegedly unrelated because Groups XIV/XV do not depend on Group XVI/XVII to function and vice versa. Group XIV/XV are to a method of monitoring the therapeutic treatment of disease in a patient. Groups XVI/XVII are to a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease.

Groups XIV/XV and XVIII/XIX are allegedly unrelated because Groups XIV/XV are drawn to a method of monitoring the therapeutic treatment of disease in a patient, while Groups XVII/XIX relate to a kit used to diagnose a disease and a kit used to identify polypeptides.

Groups XIV/XV and XX are allegedly unrelated because Groups XIV/XV do not depend on Group XX to function and vice versa. Groups XIV/XV are drawn to a method of monitoring the therapeutic treatment of disease in a patient, while Group XX relates to a transgenic or knockout non-human animal.

Groups XVI/XVII and XVIII/XIX are allegedly unrelated because Groups XVI/XVII do not depend on Group XVIII/XIX to function and vice versa. Groups XVI/XVII are drawn to a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease. Groups XVIII/XIX are drawn to a kit used to diagnose a disease and a kit to identify polypeptides.

Groups XVI/XVII and XX are allegedly unrelated. The Office Action states that Groups XVI/XVII do not depend on Group XX to function and vice versa. Groups XVI/XVII are to a method for identifying a compound that is effective in the treatment and/or diagnosis of a disease, while Group XX relates to a transgenic or knockout non-human animal.

Groups XVIII/XIX and XX are allegedly unrelated because Groups XVIII/XIX do not depend on Group XX to function and vice versa. Groups XVIII/XIX relate to a kit used to

diagnose a disease and a kit to identify polypeptides. Group XX is to a transgenic or knockout non-human animal.

The MPEP lists two criteria for restriction to be proper. First, the invention must be independent or distinct. MPEP §803. Second, searching the additional invention(s) must constitute an undue burden on the Examiner if restriction is not required. *Id.* The MPEP directs the Examiner to search and examine an entire application "[i]f the search and examination of an entire application can be made without serious burden...even though it includes claims to distinct or independent inventions." *Id.*

The Office Action alleges that "because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and that the search for one invention is not required for the search of another, restriction for examination purposes as indicated is proper". However, a number of the groups have been classified under common search classes, which contradicts the above statement. Therefore, it is respectfully submitted that at least a subset of the groups that are commonly classified should be subject to rejoinder.

For example, Groups I, V, VI, VIII, XI, XIII, XIV, and XVI were classified under class 530, subclass 350+. Groups III, IV, IX, XII, XV, XVII, and XVIII were classified under class 536, subclass 23.1. Furthermore, Groups II and VII were classified under 435, 320.1. The fact that these selected Groups fall under the same search classification indicates that it would not be an undue burden on the Examiner to search and examine the subject matter of the present invention.

The claims, as originally filed and presented herein, represent a web of knowledge and continuity of effort that merits examination as a single invention. Additionally, a search of the commonly classified Groups is necessarily believed to be coextensive, as searches of the subject matter of Groups I, V, VI, VIII, XI, XIII, XIV, and XVI; Groups III, IV, IX, XII, XV, XVII, and XVII; as well as Groups II and VII would consequently and inextricably encompass a search of the claims included in each Group that encompasses a common classification.

Accordingly, as Applicants have elected the claims of Group I, with traverse, Applicants request that Group I be rejoined with those Groups similarly classified, such that the claims of Groups I, V, VI, VIII, XI, XIII, XIV and XVI are searched and examined together.

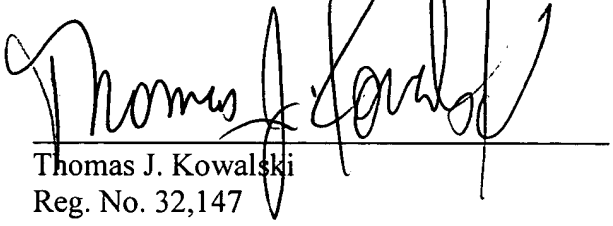
In view of the remarks herein, enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially in view of the requisite showing that a serious burden has not been met. Indeed, the search and examination of each commonly classified Group would likely be co-extensive and, in any event, would involve such interrelated art that search and examination of the entire application can be made without undue burden on the Examiner. All of the preceding, therefore, mitigate against restriction.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal, or at least modification, of the restriction requirement, such that, at the least, the claims of Groups V, VI, VIII, XI, XIII, XIV, and XVI are searched and examined with the claims of Group I.

CONCLUSION

Reconsideration and withdrawal, or modification of the restriction requirement, and a prompt and favorable examination on the merits, is respectfully requested.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: 

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